IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: SERZONE
PRODUCTS LIABILITY LITIGATION

MDL NO. 1477

THIS DOCUMENT RELATES TO CLASS ACTION SETTLEMENT

MEMORANDUM OPINION AND ORDER APPROVING SETTLEMENT AND CERTIFYING THE SETTLEMENT CLASS

Pending before the court is the plaintiffs' motion for final approval of class action settlement [Docket 209]. This litigation arises from allegations that Serzone, a drug used to treat depression, caused a range of physical and economic injuries among users and purchasers. On August 12, 2002, this court acquired jurisdiction over the Serzone litigation by transfer order of the Judicial Panel on Multidistrict Litigation. The case developed in discovery for over a year, and settlement discussions began in mid-2003. On October 28, 2004, the plaintiffs moved for preliminary approval of a class action settlement, which the court granted on November 18, 2004. Upon completion of notice of the settlement and submission of written comments to the court in favor of and opposed to the settlement, the court held a final fairness hearing on June 29, 2005. Having considered the entire record of submissions in this matter and the oral presentations at the final fairness hearing, I **FIND** that the settlement class satisfies the requirements of Rule 23(a) and Rule 23(b)(3). Moreover, I **FIND** that the settlement is fair, reasonable, and adequate. Accordingly, the plaintiffs' motion for final approval of the class action settlement is **GRANTED**.

I. Background

Bristol-Myers Squibb Company (BMS) developed Serzone, empirically known as nefazodone hydrochloride, to treat depression. In pre-market trials conducted by BMS, sixteen percent of the 3,496 patients who used Serzone had to discontinue its use because of an adverse experience, including abnormal liver function test results. The Food and Drug Administration nevertheless approved BMS's New Drug Application for Serzone on December 22, 1994 based upon findings that Serzone met standards of safety and efficacy as a treatment for depression.[1] BMS began commercial sales of Serzone on March 15, 1995. Serzone's initial label had standard warnings as to the various potential side effects that had been reported during pre-market trials. The label listed hepatitis as a "rare" adverse event and abnormal liver function as an "infrequent" event.

In 1998, following reports of additional problems, BMS submitted an application to the FDA to revise Serzone's label to state that BMS had received "rare reports of liver necrosis and liver failure, in cases leading to liver transplantation and/or death." BMS investigated the causal association between Serzone and liver failure by conducting two studies – one in 1999 and 2000 and another in 2000 and 2001. The 1999-2000 study found no incidence of liver failure in approximately 30,000 patient years of Serzone use. The 2000-2001 study did not find Serzone associated with an increased rate of liver failure as compared to that of other antidepressants. Despite these particular findings, in July 2001, the FDA directed BMS to issue a "Dear Doctor" letter to communicate to health professionals that cases of life-threatening hepatic failure had been reported in patients treated with Serzone. The FDA further required BMS to change Serzone's

1 As stated in Serzone's product label, only two of eight pre-market trials conducted by BMS demonstrated that Serzone was effective in the treatment of depression.

labeling to include a black box warning, the most serious warning used in prescription labeling. The revised label cautioned:

> The reported rate in the United States is about 1 case of liver failure resulting in death or transplant per 250,000 - 300,000 patient years of Serzone treatment. This represents a rate of about 3 - 4 times the estimated background rate of liver failure. This rate is an underestimate because of under reporting, and the true risk could be considerably greater than this. A large cohort study of antidepressant users found no cases of liver failure leading to death or transplant among Serzone users in about 30,000 patient years of exposure. The spontaneous report data and the cohort study results provide estimates of the upper and lower limits of the risk of liver failure in nefazodone treatment patients, but are not capable of providing a precise risk estimate.

Given entry of generic forms of nefazodone into the market and the declining volume of branded sales, BMS discontinued the manufacture and sale of Serzone on June 14, 2004. That same day, the FDA declined to remove Serzone from the United States market and issued the following statement:

> The Agency believes: (1) nefazodone may provide an important alternative to other antidepressants; (2) although there is a risk of liver injury associated with nefazodone, the incidence of liver failure appears to be low; . . . (4) the black box warning adequately addresses liver toxicity overall . . . .

Nefazodone hydrochloride manufactured by entities other than BMS remains on the market as the FDA continues to believe that its risk-benefit profile supports its continued use in certain patients.

According to David Dunner, M.D., one of BMS's medical experts, the causes of depression are not fully understood. (Dunner Aff. ¶ 9, June 9, 2005).[2] Research indicates that it has biological, genetic, environmental, and psychological bases. *Id.* at ¶ 9. The biological basis has

2 Affidavit of David L. Dunner, M.D., a professor of Psychiatry and Behavioral Sciences and Director of the Center for Anxiety and Depression at the University of Washington. Dr. Dunner's affidavit was uncontested in either the written objections or oral objections at the fairness hearing.

been linked to imbalances of certain neurotransmitters in the brain, particularly serotonin and norepinephrin. *Id.* at ¶ 11. Drugs like Tofranil, Prozac, and Serzone have been developed to correct these imbalances. *Id.* at ¶¶ 12 & 13. Each of these drugs, however, uses a different mechanism of action to achieve desired results. *Id.* For example, Selective Serotonin Reuptake Inhibitors (SSRIs), like Zoloft and Prozac, regulate serotonin levels by blocking the ability of nerve endings to bind and break down serotonin. Serzone utilizes a different mechanism of action that affects two specific receptors to regulate serotonin levels. Serzone also has effects on the norepinephrine receptors. *Id.* at ¶ 3.

Accordingly, not all antidepressants work equally well in all patients. *Id.* at ¶ 14. Antidepressants not only operate by different mechanisms of action, but they also carry different side effects, and presentation of these effects varies among individual patients. *Id.* Treatment of depression with drug therapy thus boils down to a process of patient monitoring and trial and error to determine which available antidepressant functions best to restore a patient to well-being.[3] Because the availability of a variety of medications increases the odds of finding the right treatment for depression in a particular individual, nefazaodone remains on the market despite its considerable risks, and its required use of the FDA's black box warning.[4]

Similar to the unknowns surrounding the origins and treatment of depression, liver disease can be idiosyncratic and difficult to diagnosis. (Watkins Aff. ¶ 19, June 3, 2005).[5] This is due in

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3 It is appropriate to note that in clinical trials, Serzone's profile of side effects was typically more favorable, especially with respect to weight gain, sexual dysfunction and sleep disturbance, than those of other antidepressants. (Dunner Aff. ¶ 27, June 9, 2005). Serzone's favorable weight gain side effect makes it useful in treating depression in women, who are more sensitive to the negative self image associated with weight gain. *Id.* at ¶ 32. Notably, twice as many women as men are diagnosed with depression each year. *Id.*

4 As declared in Dr. Dunner's affidavit, "The favorable side effect profile of Serzone, coupled with its overall efficacy in treating depression, have made it an important addition to the medications available to psychiatrists to treat depression." (Dunner Aff. ¶ 33, June 9, 2005)

5 Affidavit of Paul B. Watkins, M.D., a physician licensed in North Carolina and board certified in Internal

large part to the important role that the liver plays in many of the body's essential functions. *Id.* at ¶ ¶ 6,7, &8. The liver stores nutrients, helps control certain hormone levels in the blood, and produces important substances like those that allow blood to clot and those that aid in the digestion of fats. *Id.* at ¶ 6. Most importantly, the liver filters all the blood from the digestive tract before it goes to the rest of the body. *Id.* at ¶ 7. Accordingly, the liver must deal with both beneficial and harmful components carried in the blood. *Id.* The liver breaks down nutrients into molecules necessary for the production of energy and other critical functions, and it metabolizes potentially harmful substances, like alcohol, industrial chemicals, artificial food additives, and street drugs to protect the rest of the body from their effects. *Id.* Most medications are also metabolized through the liver. *Id.* at ¶ 8. This function helps rid the body of medications that would otherwise remain for undesirable amounts of time. *Id.* In addition, the true acting agent of a drug may be a metabolic by-product; thus, performance of a drug may even depend on the liver to first metabolize the drug. *Id.*

According to Paul Watkins, M.D., there are many ways the health of the liver can be adversely affected by toxins, drugs, or diseases. *Id.* at ¶ 11. Certain viruses such as hepatitis A, B, and C and certain autoimmune diseases such as primary biliary cirrhosis and primary sclerosing cholangitis can injure the liver. *Id.* at ¶ 9. Toxins such as industrial chemicals, certain cleaning fluids and alcohol will predictably injure the liver, depending upon the dose and duration of the exposure to these substances. *Id.* With drug-induced liver injury, however, a medication capable of causing severe liver damage in some people may cause no liver harm at all in the vast majority of patients taking the drug. *Id.* Moreover, as a general matter, idiosyncratic drug-induced liver disease manifests itself while a patient is taking the drug. *Id.* at ¶ 21. With very few exceptions, such liver

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Medicine (since 1982) and Gastroenterology (since 1984). Dr. Watkins' affidavit was uncontested in either the

disease does not present itself after the patient has stopped using the medication and the medication has left the patient's system. *Id.* at ¶ 21. Even among those patients suffering liver injury, the injury process should cease after therapy is discontinued and the drug is eliminated from the body. *Id.* at ¶ 19. As summarized by Dr. Watkins, "[I]f the patient does not die or require a liver transplant, the liver begins to regenerate as soon as the injury subsides." *Id.* at ¶ 19. Accordingly, "[i]n most instances, patients who have recovered from drug-induced liver injury without need for a liver transplant do not face any residual injury or risk of future injury, assuming they avoid the drug." *Id.* at ¶ 21.

II. Litigation History

In mid-2002, six product liability actions were filed against BMS in four federal courts: three in the Western District of Louisiana and one each in the Eastern District of Louisiana, the Middle District of Louisiana, and the Northern District of Mississippi. Finding these cases to share common issues of fact relating to the safety of Serzone, the Judicial Panel on Multidistrict Litigation issued a Transfer Order on August 12, 2002, consolidating and transferring the actions to this district for pretrial proceedings. Since then, more than 160 cases involving thousands of individual plaintiffs have been transferred to the *In re Serzone Products Liability Litigation*, MDL No. 1477. In these cases, the plaintiffs allege injuries caused by Serzone ranging from liver failure resulting in transplant or death to drug-induced hepatitis, nausea, dizziness and diarrhea. Some plaintiffs claim that Serzone lacked efficacy as an antidepressant, and some allege that its price was too high. A core allegation in these actions is that BMS misrepresented or omitted material facts about Serzone,

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written objections or oral objections at the fairness hearing.

including the adverse health effects caused by Serzone and the frequency, severity and rapid development of those adverse effects.

On August 16, 2002, I issued Pretrial Order No. 1, which scheduled an initial status conference for September 23, 2002 to address case management issues and to identify critical facts and legal issues [Docket 2]. The order also informed the parties of the court's website, http://www.wvsd.uscourts.gov/serzone/, where significant orders and opinions would be published. *Id.* On September 25, 2002, I referred this matter to Magistrate Judge Mary E. Stanley for management of discovery and resolution of discovery disputes [Docket 6]. In Pretrial Order No. 2, issued on October 7, 2002, I appointed Carl N. Frankovitch of Anetakis, Colantonio & Simon and Marvin W. Masters of the Masters Law Firm, as Plaintffs' Co-Lead and Co-Liaison Counsel [Docket 8]. In turn, I appointed Michael A. Tanenbaum of Sedgwick, Detert, Moran & Arnold LLP as Defendant's Lead Counsel and Michael Victorson of Jackson Kelly PLLC as Defendant's Liaison Counsel. *Id*. Lastly, I set forth a discovery schedule and appointed members to a Plaintiffs' Executive Committee to conduct and coordinate the discovery stage of this litigation with defendant's representatives. *Id.*

To further manage discovery, Judge Stanley designated a Discovery Committee consisting of counsel for plaintiffs and BMS.[6] Judge Stanley conducted numerous conferences regarding discovery matters, and on December 6, 2002, the plaintiffs served BMS with their comprehensive request for production of documents. The request was organized into nine categories: (1) corporate data; (2) government regulatory documents; (3) product testing; (4) withdrawal from the market; (5) labeling; (6) marketing; (7) physicians and scientists; (8) healthcare insurers and pharmacies; and (9)

6 The Discovery Committee is distinct from the Plaintiff's Executive Committee, but the two groups were

other documents concerning the litigation [Docket 11, 14, 15, & 21]. BMS made an initial voluntary disclosure of documents in electronic form in November, 2002, and on January 27, 2003, BMS served its responses to the plaintiffs' requests. BMS continued to produce documents on a rolling basis through March, 2004. Negotiations regarding individual plaintiff discovery culminated in court approval of a Plaintiff's Fact Sheet and related medical and other record authorizations on January 7, 2003 [Docket 41]. In total, between November, 2002 and March, 2004, BMS produced over one and one half million pages of documents, which were analyzed by the Discovery Committee. Concurrently, the Plaintiffs' Executive Committee undertook a detailed analysis of all Serzone adverse event reports.

In mid-2003, settlement negotiations began. On August 7, 2003, the plaintiffs met with BMS representatives in New York where they proposed that the parties investigate the potential for a global resolution based on the severity of the claimants' injuries and a simplified formula of causation. After a year of negotiations, the parties reached an agreement in principle to a class action settlement in the aggregate amount of $70 million, subject to certain increases. On October 28, 2004, the plaintiffs moved for preliminary approval of the class action settlement, which the court granted on November 18, 2004. Counsel for the parties were ordered to implement the Settlement Notice Plan and to establish an interactive website on which notice materials could be accessed by prospective Class Members. I also invited Class Members and interested parties to submit written comments in favor of, or in opposition to, the settlement and to file a written notice of appearance to speak at the final fairness hearing. After considering the required factors in Fed. R.

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directed to work in conjunction with one another.

Civ. P. 23(g), I appointed Carl N. Frankovitch, Marvin W. Masters, Dianne M. Nast and Stanley M. Chesley as Class Counsel.

In addition, on November 18, 2004, I issued an opinion regarding attorneys' fees. The order directed that any contingency fee agreement between an individual class member and an attorney that has or will be entered into after October 15, 2004, and is intended to allow the attorney to recover contingency fees, will not be enforced. Such counsel may instead seek reimbursement only at an hourly rate that does not exceed $200.00 per hour for a total amount of compensation that does not exceed $10,000 [Docket 171]. In December, 2004, I issued another opinion regarding individual notice and privacy interests. The order directed BMS to provide individual notice to all reasonably identifiable Class Members, namely the plaintiffs and individuals who had been the subject of a Serzone-related Adverse Event Report (AER). I also directed BMS to provide notice to physicians who had submitted Serzone-related AERs. To reconcile the countervailing interest in protecting individual privacy with the interest in providing potential Class Members with the best notice practicable, I directed BMS to distribute the mailings itself to avoid unnecessary administrative involvement of any party previously unaware of the AER reports [Docket 176]. I later amended that order to direct that notice be sent to known counsel as well [Docket 183].

On June 29, 2005, I held a final fairness hearing. Prior to the fairness hearing, seventeen objections and eight notice of appearance were filed.[7] Two groups of insurers and a group of six

7 The following groups and individuals filed objections: Blue Cross Blue Shield Plans; David Pentz; Marty Register, Rebecca Hite, William Sloan, John Parrish, William Huseman, and Lucy Carle; Third Party Payers; Bruce Davidson, M.D.; William Edwin Collard, Jr.; James Martin; Hugh Rice Kelly; Kenneth Gauntlett; Lummus Hannes; Mary Mullen; Johnnie Davidson; Rebecca Long; Craig Albritton; Pam Barnett; Anthony Caputo II; and David Storm, St. Those filing notices of appearance include: Blue Cross Blue Shield Plans; David Pentz; Marty Register, Rebecca Hite, William Sloan, John Parrish, William Huseman, and Lucy Carle; Johnnie Davidson; Rebecca Long; Ron Penton; Daniel Becnel; and Dexter Heir. William Edwin Collard, Jr. has withdrawn his objections. There is no evidence in the record to indicate that the withdrawal is connected to any benefit conveyed or promised by Plaintiffs' Counsel or BMS to Mr. Collard.

Class Members also filed motions to intervene.[8] Class Counsel and counsel for BMS filed briefs, affidavits, and other documents in support of the class action settlement. They also filed responses to the various objections filed with the court during the course of the notice. At the hearing, counsel for each party was given an hour to speak. Arthur Miller appeared as additional counsel for the class and argued in favor of the settlement. All persons who filed a written notice of appearance were recognized and allowed to speak about their concerns.[9] Moreover, I gave each objector the opportunity to file a supplemental brief within ten days of the hearing and counsel to file any responses within five days after. Two objectors filed supplemental briefs, and BMS and Class Counsel responded to each brief. I have carefully considered the issues and concerns raised both at the fairness hearing and in writing before and after the hearing. I will discuss these issues at length below.

III. The Proposed Settlement

A. Class Members & Basic Terms

On November 4, 2004, Class Counsel filed a complaint in the Southern District of West Virginia to streamline the claims of Class Members asserted in pending federal and state Serzone litigation throughout the country and to facilitate class action treatment of those claims for settlement purposes. The named plaintiffs consisted of Dexter Heir, Andrea Harper, Martha Sue Perdue, Cecil Gladwell, and Susan K. Kyle.[10] The complaint invoked diversity jurisdiction and

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8 The motion to intervene filed by Marty Register, Rebecca Hite, William Sloan, John Parrish, William Huseman, and Lucy Carle was filed for purposes of objecting. Finding this procedural step unnecessary, I denied this motion at the fairness hearing but allowed them to present their objections. The insurers have since withdrawn their motions and objections.

9 The following individuals spoke at the fairness hearing: Edward Cochran representing John Parrish; Frank Tomlinson representing Rebecca Hite; Albert Bacharach representing Rebecca Hite; John Pentz representing David Pentz; Rebecca Long (pro se); Daniel Becnel (commenting in favor of proposed settlement).

10 The instant case has been assigned case number 2:04-cv-1188. Two of the named plaintiffs had previously filed suit against BMS: (1) Dexter Heir filed suit on May 21, 2004 in the District of Minnesota; and (2) Susan Kyle

asserted various state-law claims for relief, including: (1) strict products liability (failure to warn); (2) strict products liability (design defect); (3) negligent failure to warn; (4) negligence per se; (5) breach of implied warranty; (6) breach of express warranty; (7) unjust enrichment; and (8) fraud. BMS's answer denied the principal allegations of the complaint and asserted fifty-seven affirmative defenses.

The Settlement Agreement, which has been presented for the court's approval, is between BMS and the following class:

> All natural persons in the United States and its territories who purchased or used Serzone in the United States and its territories between March 15, 1995 and October 1, 2004, and their estates, administrators or other legal representatives, heirs or beneficiaries. It includes all other persons or entities asserting the right to sue BMS or any of the Released Parties by reason of their relationship with a person who purchased or used Serzone.
>
> The Settlement Class does not include any individuals whose claims against BMS or any other of the Released Parties arising from Serzone have been resolved by release outside of this Settlement or by judgment on the merits.

Third Amended Settlement Agreement at ¶¶ 6-7.[11] The Settlement waives any statute of limitation defense and simplifies issues of causation by conditioning recovery on objective criteria. Specifically, the settlement conditions payment only on (1) submission of proof of use or purchase of Serzone; and (2) for those claiming a specific physical injury, proof of a temporal relationship between the use of Serzone and a qualifying medical condition. Counsel for both BMS and the

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filed suit on June 24, 2003 in the Northern District of West Virginia.

11 The Settlement Agreement dated October 15, 2004 was subsequently amended three times in order to: (1) conform to the court's preliminary approval order dated November 24, 2004; (2) extend the time frame for BMS to make initial deposits to the claim funds in accordance with the court's order dated December 30, 2004; (3) ensure the security of the Settlement Funds, conform to the rules of prudent investment for funds of this nature, and clarify procedures related to the administration of claims and payments to the Claims Administrator pursuant to the court's order dated February 15, 2005.

plaintiffs agree that drug-induced liver failure causes immediate rather than delayed harm. As such, this litigation presents no risk of latent effects or future claims. The Settlement Agreement establishes October 1, 2004 as the cut-off date for persons who have purchased or used Serzone to be included in the Class. BMS discontinued the manufacture and sale of Serzone on June 14, 2004, and both sides assert that no new injuries will occur due to Serzone ingestion because of the way Serzone affects the body. Moreover, those injuries already alleged should not progress among Class Members.

B. Settlement Funds

The Settlement Agreement allocates $70 million to pay qualifying claims and guarantees an additional pool of $8 million to draw upon if there is an unexpectedly high volume of the most serious injury claims. In that situation, the Agreement provides for additional and discretionary Back End Adjustments to ensure that the funds can cover the qualifying claims. Class Members who participate and qualify for Fund A or Fund B payments will also have a "Back End Opt-Out right" in the unexpected event that funds run short.

As the parties have structured the settlement to utilize a Qualified Settlement Fund as defined in section 1.468B-1(c) of the Treasury Regulations, any funds remaining after the actual payment of all Fund A and B claims will not be returned to BMS but rather transferred to a sub-account. This sub-account, under the terms of the Qualified Settlement Fund, is dedicated to the payment of a spectrum of claims, including any award of fees to Class Counsel. This financial arrangement provides for protection of the funds and confers certain tax benefits for Class Members and BMS. In no event, however, will any of the money deposited into the Fund be returned to BMS.

The Schedule of Payments details the financial terms of payments to Class Members. The Schedule recognizes four categories of injuries as well as gradations of injury within each category. Based on objective medical criteria, it makes payments from four corresponding funds: Fund A, Fund B, Fund C, and Fund D. Funds unused by B, C, and D claimants will go to pay Fund A claimants, if necessary. Likewise, funds unused by A, C, and D claimants will go to pay Fund B claimants, if necessary.

Fund A, initially funded with $30 million, provides two separate schedules of compensation for claimants with "serious hepatic injuries." Claims qualifying as "serious hepatic injuries" include death, liver failure requiring transplant, and liver failure requiring placement on the UNOS transplant list but no transplant occurred. One schedule provides payment to claimants who had no pre-existing liver problem, and the other provides compensation to claimants who had chronic liver disease before or during use of Serzone or who had other medical conditions that complicate matters of medical causation. Payments range from a high of $3.5 million for the representatives of 30 to 40 year old patients who died from acute liver failure to $100,000 for claimants with pre-existing liver problems who developed acute liver failure and were placed on the UNOS transplant list, but who did not undergo transplant surgery.

Fund B, initially funded with $30 million, also provides two separate schedules of compensation for claimants with "general hepatic injuries." The Schedule defines "general hepatic injury" to include hepatic injuries reflected by laboratory abnormalities, overt symptoms such as jaundice, and significant medical treatment consisting of either hospitalization or repeated out-patient visits. One schedule provides payment to claimants without any pre-existing liver disease, and the other provides compensation to claimants with pre-existing liver disease or who had other

liver conditions. The schedule provides for a maximum of $200,000 for young claimants with significant laboratory abnormalities who required hospitalization to a minimum of $5,000 for claimants with other confounding medical conditions who showed elevated liver enzymes by two consecutive blood tests no closer than two days and no further than ninety days apart.

Fund C, funded with $5 million, provides compensation for "non serious hepatic injuries." The Schedule defines "non serious" injuries by reference to laboratory tests reflecting elevated liver enzymes or bilirubin. Fund C provides for two levels of payments: $7,500 for more significantly elevated readings and $2,000 for less significantly elevated readings. Fund C does not require any overt physical symptoms of clinical illness. Fund D, the "non specific injury and general benefit fund," is also funded at $5 million. It provides a payment of $100 to any claimant who wants to make a claim for any reason, and who can prove that he or she bought or used Serzone during the class period. It requires no showing of overt physical or economic injury.

The Schedule of Payments also provides for additional payments based on claimant-specific factors. In Fund A, it allows increases of twenty-five percent for multiple liver transplant surgeries. The Schedule further provides for a $100,000 payment for spousal loss of consortium, and allows $100,000 awards for loss of support to each child under the age of eighteen who has lost a parent to liver disease. The Schedule also provides for payments of up to $50,000 annually for loss of income for up to a maximum of fifteen years. In Fund B, the Schedule allows for payments of up to $50,000 annually for loss of income for up to a maximum of two years.

If Fund A or Fund B claims and expenses exceed the available amounts in these respective funds, the Settlement Agreement further provides for Back End Opt-Out and Adjustments. For Fund A, BMS will pay up to an additional $5 million to pay all approved Fund A claims at the full value

assigned to them by the Claims Administrator. If $35 million is still insufficient to pay Fund A claims at one hundred percent of the value assigned to them by the Claims Administrator, BMS can increase the funding again. BMS may also decline to increase the dollar amount in Fund A beyond the additional $5 million. If that is the case, BMS and Class Counsel have agreed to negotiate in an attempt to agree on a reduced payment that will be accepted by approved Fund A claimants. Under the terms of the Settlement Agreement, the parties must report the results of their good faith negotiations to the court.

If I approve the new negotiated payments, the Claims Administrator must notify each Fund A claimant of his or her revised award. If the revised award varies by more than five percent from the amount to which the claimant would have otherwise been entitled, the claimant will have thirty days from receipt of the revised award to exercise a Back End Opt-Out and restore his or her claim to active litigation status. If the claimant does not opt out, he or she will receive the negotiated award in full satisfaction of his or her claim. The terms of the Back End Opt-Out and Adjustment rights for Fund B are exactly the same as for Fund A, except that BMS is only obligated to pay an additional $3 million, as opposed to $5 million for Fund A, to meet approved claims.

In the event that I determine that BMS and Class Counsel are unable to reach an agreement as a result of their reduced payment negotiations for Fund A or Fund B, or if the parties reach an agreement that I do not approve, the Settlement Agreement will terminate only with respect to the involved fund. All money remaining in the involved fund will be transferred to the BMS Product Liability Sub-Account. Under the terms of the Settlement Agreement, if Fund C or Fund D claims and expense totals exceed the available amounts in these respective funds, benefits to Class

Members will be proportionately reduced. BMS will not make any Back End Adjustments to these two funds, nor do claimants under these funds have any Back End Opt-Out Rights.

C. Claims Administration

The settlement agreement provides for a two-stage claims process. The first stage required claimant Class Members to submit a preliminary form providing minimal information about their claims so that the parties could predict where a particular claimant may fall in the settlement matrix. The deadline for filing this inventory form was May 13, 2005, approximately six weeks before the date of the Final Fairness hearing. The second phase of the claims process requires the submission of full claims information, and will conclude 90 days after final judicial approval of the settlement. The claims administrator's factual determinations regarding the claims information may be appealed to the Magistrate Judge.

D. Other Payments

The Settlement Agreement also provides that BMS will pay reasonable actual expenses, not to exceed $950,000, to provide notice of the Settlement to Class Members. Additionally, attorney fees and expenses as awarded by me will be paid by BMS separate and apart from any Fund payment. In the event that any money is transferred to the BMS Product Liability Sub-Account, that money will also be available to pay attorneys' fees. Although the Settlement Agreement does not provide further detail as to limitations on attorneys' fees that may be requested by Class Counsel, the order entered by this court on November 18, 2004 conditionally certifying the settlement class and preliminarily approving the settlement indicates that Class Counsel's fees shall not exceed $20 million. Class Counsel have petitioned the court for an award of attorneys' fees, and the matter is currently under advisement. Under the terms of the agreement, distribution of attorneys' fees and

costs allowed to Class Counsel will not occur until approval of the Settlement is final and non-appealable and all of the dates upon which BMS has any option to terminate the settlement agreement or any portion thereof has passed.

IV. Personal Jurisdiction and Notice

Reasonable notice combined with an opportunity to be heard and withdraw from the class satisfies the due process requirements of the Fifth Amendment. *In re Diet Drugs Prod. Liab. Litig.*, Nos. 1203, 99-20593, 2000 WL 1222042, at **34 (citations omitted). Thus, "silence on the part of those receiving notice is construed as tacit consent to the court's jurisdiction." *Id.* (quoting *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 306 (3d Cir. 1998)). In addition, in a settlement class maintained under Rule 23(b)(3), class notice must meet the requirements of both Federal Rules of Civil Procedure 23(c)(2) and 23(e). Rule 23(e) specifies that "[n]o class action may be 'dismissed or compromised without [court] approval,' preceded by notice to class members." *Fed. R. Civ. P.* 23(e). Rule 23(c)(2) requires that notice to the class must be "the best practicable under the circumstances, including individual notice to all member who can be identified through reasonable effort." *Fed. R. Civ. P.* 23(c). The Rule also requires that the notice inform potential class members (1) that they have an opportunity to opt out; (2) that the judgment will bind all class members who do not opt out; (3) and that any member who does not opt out may appear through counsel. *Id.* Thus, I must consider the mode of dissemination and the content of the notice to assess whether such notice was sufficient. MANUEL FOR COMPLEX LITIGATION (FOURTH) § 21.312 (2004).

When I granted preliminary approval of the proposed settlement on November 18, 2004, I approved the form and method of notice described in the Notice Plan, which included nationwide publication notice, establishment of a notice and claims information website

(www.serzoneclaims.com), a toll free number to take questions, and individual mailings to reasonably identifiable Class Members. The Notice Plan was drafted by Hilsoft Notifications, a Pennsylvania firm specializing in designing, developing, analyzing and implementing large-scale, unbiased legal notification plans. Hilsoft has disseminated class action notices in more than 150 cases, and it designed the model notices currently displayed on the Federal Judicial Center's website as a template for others to follow.

Here, the Notice Program was designed to:

> (a) effectively reach approximately 80% of Class Members; (b) provide those Class Members reached multiple opportunities to be exposed to the notice; (c) use targeted notice vehicles and state-of-art notice planning (I.E., media known to be used by Class Members), with audiences that can be mathematically calculated; (d) provide thorough and fair geographic coverage of the United States and its territories and possessions; (e) design a program broadly targeting Class Members, without disadvantaging any potential Class member on the basis of geography (where they choose to live) or demographics (e.g., their age or socio-economic status); (f) develop a program consistent with other notice programs [Hilsoft has] designed that have been court-approved and that [Hilsoft has] implemented for large classes certified for purposes of settlement in federal courts, West Virginia courts, and elsewhere; (g) use high quality notification vehicles and methods in order to convey the importance of the information affecting Class Members' rights; (h) write and design Notices in plain language that will be "noticed," as well as simple, clear, easy to understand and act upon; (i) ensure that Class Members who choose to participate can conveniently act on their right to claim a payment from the settlement through repetition, a variety of distribution methods, and notice design features; and (j) ensure an overall effective effort based on all relevant communication standards.

(Hilsee Aff. ¶ 25, April 14, 2005). To enhance consumer exposure, Hilsoft studied the demographics and readership of publications among adults who used a prescription drug for depression in the last twelve months. Consequently, Hilsoft chose to utilize media particularly

targeting women due to their greater incidence of depression and heavy usage of the medication. *Id.* at ¶ 27. Between December 17, 2004 and February 22, 2005, notices appeared in a series of national magazines and more than 947 United States newspapers, having an estimated combined audience of 292,337,000 people and yielding an estimated 370,325,000 gross impressions.[12]

V. Objections

Seventeen written objections were filed prior to the Fairness hearing; seven were untimely.[13] Nevertheless, I considered each of the objections, and I allowed objectors who spoke at the final fairness hearing to present arguments outside their written objections. I also afforded each objector who spoke at the hearing the additional opportunity to file supplemental briefs within ten days of the hearing and in turn, I gave BMS and Class Counsel five days to respond. Two sets of supplemental briefs were filed; one was untimely. BMS and Class Counsel filed written responses to both.

Indeed, some objections are best characterized as merely expressing discontent with the settlement without substantive argument or presentation of evidence. Other objections were premature objections to an award of attorneys' fees to class counsel. Of those remaining, the objections may be split into three principal groups: (1) objections regarding third party payments; (2) medically-based objections; and (3) procedurally-based objections.

A. Third Party Payments

Certain insurers, known as the Blue Cross Plans and Third Party Payers, filed motions to intervene as well as objections. Neither group spoke at the fairness hearing. These insurers have since provided the court with notice of withdrawal of their motions and objections as they have

12 The Summary Notice appeared in *People*, *Readers Digest*, *Family Circle*, *Better Homes and Gardens*, *Cosmopolitan*, and the *National Enquirer*.

13 In an order dated June 23, 2005, I directed that the date stamped as "RECEIVED" on the documents by the Claims Administrator be deemed as the date filed with the Clerk of Court in accordance with this court's Order

reached an agreement with BMS and Class Counsel separate and apart from the Settlement Agreement. A summary of the agreement was included in the notice of withdrawal for informational purposes. In pertinent part, it provides:

> Class Counsel and counsel for certain Insurers have agreed to a minimum 33 1/3 % discount for relevant medical liens. Class Members will be informed of the discount through a Court approved letter, to be sent by the Claims Administrator. This information will be confidential and HIPAA compliant. As an additional benefit to Class Members, participating insurers have agreed to waive their lien rights as to Fund D claimants.

A copy of the letter to be sent to Class Members was filed as an attachment to the notice of withdrawal. The letter merely informs Class Members that they are eligible to receive a discount for what may otherwise constitute subrogation claims or liens for medical benefits paid if they elect to provide information to the insurers who have entered into the agreement with BMS. I **FIND** the agreement does not unduly burden or prejudice Class Members. Rather, it gives Class Members the option of receiving a discount for certain medical liens that may attach to recoveries in any event by operation of law. Accordingly, I **APPROVE** the withdrawal of the Blue Cross Plans and Third Party Payer's motions to intervene and objections.

B. Medically-Based Objections

The medical objections before the court, filed by Rebecca Long, Johnny Davidson, Ken Gauntlett, Craig Albritton, James Martin, Pam Barnett, and the withdrawn objection of William Collard, all suggest that the Settlement should give greater compensation to persons with medical problems besides acute liver failure. The medical conditions complained of – namely headaches, loss of hearing, loss of eyesight, serotonin syndrome, primary sclerosing cholangitis – have multiple

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Conditionally Certifying Temporary Class Settlement and Preliminarily Approving Settlement [Docket 257].

causes and have not generated litigation even from these objectors. Class Counsel consulted with medical experts to address each medical objection. The consulting experts have opined that none of the objections would render the Settlement unfair or unreasonable from a medical standpoint. (Regan Aff. ¶ 15, June 8, 2005); (Heckman Aff. ¶ 14, June 8, 2005). For instance, with regard to whether drug-induced acute liver injury is either latent or whether it progresses in most former patients, the objectors presented no evidence from studies or experts. Moreover, none of the objectors attempted to cross-examine the parties' scientific experts, challenge their credentials, or question their opinions beyond mere assertions in their briefs or oral arguments.

When objectors seek individual terms more favorable than those applicable to other class members, they should be approved only on a showing of a reasonable relationship to facts or law that distinguish the objector's position from other class members. MANUEL FOR COMPLEX LITIGATION (FOURTH) § 21.643 (2004). None of the objectors have made such a showing. Nor have any of the objectors identified a distinction that requires a subclass or otherwise uncovers an imperfection in the class definition or the settlement terms. As such, perhaps the most appropriate remedy for these objectors would have been to opt out and seek recovery in the tort system.

C. Procedural Objections

1. Claims Process

Objectors argue that the lien hold-back provisions of the settlement agreement are unreasonable. The lien hold-back provisions of the Settlement Agreement reflect the acknowledgement that certain third parties may have valid liens against some claimants. These provisions are arguably designed to protect Class Members by providing an incentive for them to conduct at least some investigation as to whether their claim awards are subject to liens. Should

Class Members accept and spend their recoveries in this action without making this basic inquiry, certain Class Members might find themselves later being notified of liens of which they were unaware and might not be in the financial position to pay. To the extent that such a lien exists, it is often easier for claimants to negotiate a reduction with the lienholder up front, rather than to become embroiled in litigation pursued by the lienholder at a later time. Moreover, absent repayment of liens, BMS could, under certain circumstances, retain a liability for lien payment after the claimants have spent their settlement check elsewhere.

Some objectors assert that the vagueness of the provisions render the claims administrator nothing short of a collection agency because it calls upon the claims administrator to act even upon unrelated liens. Read in context, however, with the exception of child support, the lien provisions included in the Settlement Agreement pertain to liens associated with Class Members' purchase or use of Serzone. The examples that are provided in the Settlement Agreement include liens associated with Class Members' treatment for injuries and Medicare liens under the Medicare Secondary Payment Act. As counsel for BMS made clear during the final fairness hearing, unrelated liens are not contemplated by the Settlement. In some states, unpaid child support attaches as a lien to certain settlements. Moreover, there are numerous federal and state lien requirements for medical treatment for which plaintiffs may be responsible. The parties assert that the Claims Administrator understands the purpose of the hold-back provision, and does not aspire to act as a collection agency for debts unrelated to this action. Ultimately, I **FIND** that the lien hold-back provisions provide at least some protection to Class Members without imposing an unreasonable burden on their recovery. Also, I **FIND** it unnecessary to adopt the language changes proposed by the objectors. These objections are **OVERRULED**.

Some objectors also argue that the inventory requirement is essentially an unreasonable claims deadline. BMS responds that this requirement provides important protection to both BMS and Class Members. For the following reasons, I find that the inventory claim form was a necessary and reasonable requirement. The settlement commits Class Members and BMS to a claims process that will last for several months and cost a substantial amount of time and money. All parties have an interest in completing this process in a timely and predictable manner. Consider, for instance, the scenario in the silicone gel breast implant settlement class action in which thousands more claims were made than anticipated. In *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV94-P-11558-S, MDL 926 (N.D. Ala. Sept. 1, 1994), the settlement fund was inadequate to compensate all of the claimants, and a large number of claimants exercised their back end opt-out right in order to pursue their claims through traditional tort litigation. The principal defendant filed for Chapter 11 bankruptcy reorganization, and the class settlement simply fell apart. Mary J. Davis, *Toward the Proper Role for Mass Tort Class Actions*, 77 OR. L. REV. 157, 187 (1998).

The parties here sought to protect against this undesirable scenario by requiring the filing of an inventory form as part of the claims process. Similar procedures have been approved by at least one other MDL court. In the Chattem Dexatrim Settlement, class members were required to submit completed claims forms by July 7, 2004. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 227 F.R.D. 553, (W.D. Wash. 2004) (attached class action settlement agreement Exh. A Annex III). Notice occurred between May 24th and June 22, 2004, and the fairness hearing occurred on August 26, 2004. *Id.* at 557. In that case, the class members had a significantly shorter period of time to file their claims, which required more onerous submissions than the filing of the inventory form in the instant action. *Id.*

Based on the responses received from the filing of inventory forms, BMS believes that it has adequately funded the settlement and that the claims process can proceed with a greatly reduced risk of disruption or complete breakdown, as experienced in the silicone gel breast implant case. *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV94-P-11558-S, MDL 926 (N.D. Ala. Sept. 1, 1994). Class Members have timely filed 6,524 inventory forms. Only 61 forms were filed untimely, a relatively low number that supports the notion that the filing procedure and deadline were not overly burdensome. Even so, any claimant who filed an inventory form late, but can show that allowance of his or her late-filed claim will not cause harm or prejudice to existing parties will be allowed to join the class.

Some objectors also compare the claims administration process to an administrative proceeding, arguing that review of the Magistrate Judge's findings by an Article III judge is constitutionally required. Yet, the objectors cite no case law to support this comparison, and the court has not located relevant authority. Thus, as a practical matter, the parties have only agreed to a limited right of appeal. Accordingly, this court will retain jurisdiction to ensure that the Claims Administrator interprets the settlement correctly and fulfills its obligations, but it will not review individual matrix awards. Objectors also argue that fees should be awarded to Class Members who successfully challenge a decision by the Claims Administrator, but again, they do not cite legal authority. In turn, neither the court nor BMS or Class Counsel have been able to locate any precedent for such action. I recognize that this is a carefully negotiated compromise of claims between private litigants, and BMS has simply not agreed to pay attorney's fees for claimants who successfully exercise their limited right of appeal. Accordingly, these objections are **OVERRULED**.

Lastly, in regard to claims administration procedures, objectors point out that the third Amended Settlement Agreement reads that a showing "beyond a reasonable doubt" is required for the Magistrate Judge to overturn the Claims Administrator's determination. During the fairness hearing, however, I stated that "beyond a reasonable doubt" was not an appropriate standard in the civil law and explained that "clear error" was a similar standard that could be substituted. Neither BMS nor Class Counsel object to substituting "clear error" in place of "beyond a reasonable doubt." As I find "clear error" to be the appropriate standard, I **SUSTAIN** this objection and **ORDER** the parties to substitute "clear error" where the language reads "beyond a reasonable doubt" in the Third Amended Settlement Agreement.

3. Notice

Objections to the notice provided in this matter may be split into two groups: (1) notice regarding the right to opt-out; and (2) the relationship between the claims filings and the adequacy of the notice. Regarding the right to opt-out, one objector argues that the information requested to allow a class member to opt-out – namely the nature of alleged Serzone-related injuries and the name and address of counsel – impermissibly burdened this constitutional right. As stated by the United States Supreme Court, "the interests of absent plaintiffs are sufficiently protected . . . when those plaintiffs are provided with a request for exclusion that can be returned within a reasonable time to the court." *Philips Petroleum Co. v. Shutts*, 472 U.S. 797, 814 (1985). Under this standard, I **FIND** the argument regarding the burden of providing the information requested in the opt-out to be unpersuasive. Providing information regarding the Serzone-related injury and the name and address of counsel, if any, does not impermissibly burden a claimant's ability to return the request for exclusion within a reasonable time. Moreover, as a practical matter, BMS has asserted that it does

not dispute the validity of any opt-out based on a claimant's failure to provide such information in its entirety.

One objector argues that the notice did not conspicuously disclose the date for Class Members to exclude themselves, and others object to April 8, 2005 as the deadline for opting out. The notice contained a section on "Excluding Yourself from the Settlement," and all of the different deadlines appeared in bold face type within the notice. (Hilsee Supp. Aff. ¶ 6(b), June 8, 2005). Moreover, the notice campaign began in early December, and the deadline to file opt-outs was April 8, 2005. This timeline, spanning a period of four months, is consistent with court-approved best practices for class notice campaigns. *Id.* at ¶ 6(c)vi. Accordingly, I **FIND** that there was sufficient notice leading up to the opt-out deadline.

Objectors also assert that because the settlement class could have potentially included millions of Class Members, and only 6,524 have "shown their hands" to be included in the class by filing an inventory form, the notice is inadequate. However, many factors contribute to the claims response rate. *See, e.g., Zimmer Paper Prod., Inc. v. Berger & Montague, P.C.*, 758 F.2d 86, 92-93 (3d Cir. 1985) (holding that where defendant engaged in customary and court approved notice procedure, the response rate was not determinative of the adequacy of the class notice.); 3 Alba Conte & Herbert Newberg, NEWBERG ON CLASS ACTIONS § 8.45 (4th ed. 2002)("Claims response levels will tend to vary with the circumstances, types of class notices employed, and size of individual claims involved in each case."). BMS explains that claimants, especially Fund D claimants, may have chosen not to participate for numerous reasons. For instance, claimants who do not feel aggrieved may not want to risk exposure of privacy interests. Other claimants who were helped by Serzone might find it inapposite to recover from the settlement. As Mr. Hilsee explained

in his supplemental affidavit, the adequacy of notice is measured by whether notice reached Class Members and gave them an opportunity to participate, not by actual participation. (Hilsee Supp. Aff. ¶ 6(c)(v), June 8, 2005).

Hilsee estimates that publication notice reached approximately eighty percent of the U.S. population that used Serzone and that Class Members were exposed to the Notice an average of 2.6 times throughout the Notice program. (Hilsee Aff. ¶¶ 28 & 50, April 14, 2005). With regard to the timing of the notice, Hilsee maintains that "all of the notices appeared in the publications before the end of February 2005, which allowed plenty of time for Class Members to see the Notice several times, receive and review other information, and respond accordingly before the April 8, 2005 exclusion deadline and the April 29, 2005 objection deadline. The May 13, 2005 deadline to file an Inventory form [was] another month away." *Id.* at ¶ 51. The Claims Administrator, Smith Cochran & Hicks, PLLC, reported that 6,524 inventory forms had been received by the May 13, 2005 inventory form deadline, while only 61 forms were received after that deadline. The relatively low number of late-filings supports a finding that Class Members understood the inventory requirement and the date of its deadline.

Hilsoft Communications also created a website, www.serzoneclaims.com, to which I have provided a link on the court's official website. Among other documents related to the settlement, including the Third Amended Settlement Agreement, the website provides the notice materials in English and Spanish, which could be accessed and downloaded by prospective Class Members. Hilsee reports that Hilsoft submitted the website to over 380 submission services, and as of April 13, 2005, the website had received 31,937 hits. (Hilsee Aff. ¶¶ 37 & 38, April 14, 2005).

In addition, pursuant to the court's December 21, 2004 order concerning privacy interests

and individual notice, BMS sent written notice in January and early February, 2005 to 4,016 persons known to BMS to have used Serzone and whose names appeared in BMS's Adverse Event Report database. Furthermore, in early February 2005, BMS sent letters to 2,775 physicians in the U.S. who had called the Adverse Event Reporting System regarding patients using Serzone. This letter advised them of the settlement and encouraged them to tell patients about the settlement. In seeking to mitigate privacy concerns by eliminating the involvement of unnecessary third parties, I ordered BMS to administer this portion of the notice in lieu of Hilsoft or the claims administrator. (Keller Aff. at ¶ 5, April 15, 2005).

Not one of the objectors support challenges to the adequacy of notice with any kind of evidence; rather, these objections consist of mere arguments and speculation. I have, nevertheless, addressed the main arguments herein, and I have considered all arguments when evaluating the notice in this matter. Accordingly, after considering the full record of evidence and filings before the court, I **FIND** that notice in this matter comports with the requirements of Due Process under the Fifth Amendment and Federal Rules of Civil Procedure 23(c)(2) and 23(e).

Lastly, at least one objector asserted that the settlement is under-funded. In response, the plaintiffs submitted the opinion of Harvey S. Rosen, Ph.D., an expert participant in thousands of personal injury and wrongful death cases over a period of thirty years. Dr. Rosen states that the monetary amounts set forth in the Schedule of Payments compensate most injured parties at levels that are well within the range of damage awards expected in the tort system. Taking special note of settlement provisions for direct wage and economic loss compensation, Dr. Rosen is of the opinion that the dollar amounts on the compensation grids are fair and adequate. (Rosen Aff. at ¶ 6, June 21, 2005). Moreover, BMS has stated that the response data garnered through the filing of inventory

forms indicates that each fund is adequately funded. As the record contains no contrary evidence and none of the objectors challenged any aspect of Dr. Rosen's affidavit, I **FIND** that the settlement is adequately funded.

VI. Class Certification

Regarding requirements for certification, a settlement class must meet the requirements for certification under Federal Rule of Civil Procedure 23. *Amchem Prods. v. Windsor*, 521 U.S. 591, 620 (1997). Thus, the named plaintiffs must meet the prerequisites of Rule 23(a) and at least one of the subsections of Rule 23(b). *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 423 (4th Cir. 2003). The practice in this circuit is "to give Rule 23 a liberal rather than a restrictive construction, adopting a standard of flexibility in application [that] will in the particular case best serve the ends of justice for affected parties and promote judicial efficiencies." *Id.* at 424 (quoting *In re A.H. Robins, Co., Inc.*, 880 F.2d 709, 740 (4th Cir. 1989) (holding that it was proper in determining certification to consider whether certification would "foster the settlement of the case with advantage to the parties and with great savings in judicial time and services")).

In the instant case, plaintiffs seek certification under Rule 23(b)(3), which requires that common issues predominate over individual ones and that a class action be superior to other available methods of adjudication. In evaluating whether the settlement meets the criteria of Rule 23(a) and (b), the fact of settlement is a relevant consideration, as settlement moots concern that trial would present intractable problems of management. *Id.* The Fourth Circuit has noted,

> The Supreme Court explained in *Amchem* that when dealing with a settlement only class pursuant to Rule 23(e), 'a district court need not inquire whether the case, if tried, would present intractable management problems,' which would ordinarily be necessary to satisfy Rule 23(b)(3)'s predominance requirement . . . The dissent thus ignores the lesson of *Amchem* . . . i.e., the Supreme Court's

> recognition that the subsections of Rule 23 are interactive, and not to be followed . . . in a strictly sequential fashion.

Gunnells, 348 F.3d at 440 (4th Cir. 2003). I am nevertheless mindful of the impropriety of simply finding that "if a settlement is 'fair,' then certification is proper." *Amchem*, 521 U.S. at 594 (1997). Accordingly, I will carefully consider each of the requirements for class certification in this matter.

A. Rule 23(a)

1. Numerosity

Rule 23(a)(1) requires that the class be of sufficient size that joinder of all members is "impracticable." In determining whether joinder is impracticable, a court should analyze the factual circumstances of the case rather than relying on numbers alone. *Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass'n*, 375 F.2d 648 (4th Cir. 1967). Factors to be considered are "the estimated size of the class, the geographic diversity of class members, the difficulty of identifying class members, and the negative impact of judicial economy if individual suits were required." *Christman v. American Cyanamid Co.*, 92 F.R.D. 441, 451 (N.D. W. Va. 1981); *McGlothlin v. Conners*, 142 F.R.D. 626, 632 (W.D. Va. 1992).

At the fairness hearing, Class Counsel indicated that the proposed settlement Class consists of approximately eight million people located throughout the United States and its territories. One hundred and seventy-six federal lawsuits have been filed and transferred to the MDL. A few of these suits are styled as class actions. Moreover, lawsuits are also pending in state courts. I **FIND** that the proposed class is so numerous that joinder of all members is impracticable. Accordingly, the numerosity requirement is satisfied.

2. Commonality

Rule 23(a)(2) requires a showing of the existence of "questions of law or fact common to the

class." *Fed. R. Civ. P. 23(a)(2)*. Rule 23(b)(3) requires that questions of law or fact common to the class predominate over any questions affecting only individual members. *Fed. R. Civ. P.* 23(b)(3). The Fourth Circuit has held that "[i]n a class action brought under Rule 23(b)(3), the 'commonality' requirement [of Rule 23(a)(2)] is subsumed under, or superseded by, the more stringent Rule 23(b)(3) requirement that questions common to the class 'predominate over' other questions." *Lienhart v. Dryvit Syst., Inc*. 255 F.3d 138, 147 n.4 (4th Cir. 2001) (citing *Amchem,* 521 U.S. at 609). Because this is a class action brought under Rule 23(b)(3), I will analyze the two factors together in the predominance section of this opinion. *See In re LifeUSA Holding, Inc.,* 242 F.3d at 144 (analyzing the two factors together).

3. Typicality

To satisfy the typicality requirement under Rule 23(a)(3), the "claims or defenses of the representative parties [must be] typical of the claims or defenses of the class." *Fed. R. Civ. P.* 23(a)(3). "A sufficient nexus is established [to show typicality] if the claims or defenses of the class and class representatives arise from the same event or pattern or practice and are based on the same legal theory." *In re Trazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 686 (S.D. Fla. 2004) (quoting *Kornberg v. Carnival Cruise Lines, Inc.*, 741 F.2d 1332, 1337 (11th Cir. 1984); *see also In re Diet Drugs*, 2000 WL 1222042 at *43 (E.D. Pa. Aug. 28, 2000). The class representatives and class members need not have suffered identical injuries or damages. *United Broth. of Carpenters*, 152 F.R.D. 518, 522 (S.D. W.Va. 1994); *see also Mick v. Ravenswood Aluminum Corp.*, 178 F.R.D. 90, 92 (S.D. W. Va. 1998).

In the instant case, the claims of the named plaintiffs and the Class Members arise from a single product and identical conduct – BMS's course of conduct in the development and marketing

of Serzone. The class representatives claim that they, like every other Class Member, either used or purchased Serzone, an allegedly defective drug. Also, like any member of the class, the representatives seek the maximum amount of damages immediately. Damage levels vary among the class representatives as they do among members of the class, but all are similarly aggrieved by BMS's conduct, and all assert similar claims of liability. Accordingly, I **FIND** that the claims of the class representatives are typical of those of members of the class.

4. Adequacy

The final requirement of Rule 23(a) is set forth in subsection (4), which requires that "the representative parties will fairly and adequately protect the interests of the class." *Fed. R. Civ. P.* 23(a)(4). This determination requires a two-pronged inquiry: (1) the named plaintiffs must not have interests antagonistic to those of the class; and (2) the plaintiffs' attorneys must be qualified, experienced and generally able to conduct the litigation. *Hewlett v. Premier Salons Int'l, Inc*., 185 F.R.D. 211, 218 (D. Md. 1997).

The adequate representation inquiry "serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem*, 521 U.S. at 625. The named plaintiffs seek to represent persons who have purchased or used Serzone, each of whom was impacted by BMS's alleged wrongdoing and each of whom has the same interest as the named plaintiffs in establishing BMS's liability and obtaining damages. No conflict of interest exists as all members of the settlement class desire to recover damages immediately for injuries allegedly caused by the purchase or ingestion of Serzone.

In *Amchem*, the class consisted of both injured and exposure-only plaintiffs. As such, the interests of those in the class were conflicted, and the named parties could not adequately represent

the class. For instance, the goal for currently injured plaintiffs was to obtain generous, immediate payments. The goal for exposure-only patients, however, was to ensure an ample, inflation-protected fund for the future. Given such conflicting interests, there could be no assurance of adequate representation. In contrast, here, there is no scientific evidence of latent or progressive liver injuries arising from the ingestion of Serzone nor does the class have to accommodate future claimants, as in *Amchem*. Indeed, there are no members of the class in whose interest it would be to preserve BMS's resources for the future. *See, e.g.*, *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 227 F.R.D. 553, 562 (W. D. Wash. 2004). The injuries among Class Members are presently known, and all Class Members are interested in immediate payment.

No objections indicate, and there is nothing in the record to suggest, that the representative Plaintiffs have interests antagonistic to those of the absent Class Members in the pursuit of the Class claims against BMS. I **FIND** that Rule 23(a)(4)'s first requirement is satisfied. Different levels of compensation under the settlement's Schedule of Payments do no defeat this finding. By nature of the settlement, the parties have negotiated values to assign to claims based on the severity of physical injury. I do not consider the assignment of a lower value to claims where injuries are less serious to be evidence of conflict.

The inquiry into the adequacy of legal counsel focuses on whether counsel is competent, dedicated, qualified, and experienced enough to conduct the litigation and whether there is an assurance of vigorous prosecution. *McGlothlin v. Connors*, 142 F.R.D. 626, 633-34 (W.D. Va. 1992.). Class Counsel have many years of experience in prosecuting complex products liability litigation and managing class action lawsuits. In fact, I hand selected these attorneys among several qualified attorneys to assume leadership roles in the multi-district litigation at the outset of this

matter. Informed by voluminous discovery and research, Class Counsel were able to negotiate the proposed settlement from a position of knowledge, as advocates for the entire Class. They negotiated the settlement within the context of an MDL comprising thousands of individual claims and other pending class actions. Noting that it is uncontested in the record that the named plaintiffs are represented by competent attorneys with extensive experience in mass tort litigation, I **FIND** that Rule 23(a)(4)'s second requirement is satisfied.

The proposed class action must also meet the requirements of at least one of the subsections of Rule 23(b). Under Rule 23(b)(3), a class may be certified only where "questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and . . . a class action is superior to other available methods for the fair and efficient adjudication of the controversy." *Fed. R. Civ. P.* 23(b)(3). In the context of granting approval to a proposed class settlement, settlement is relevant to the predominance inquiry. *See Amchem*, 521 U.S., at 620 ("[A] district court need not inquire whether the case, if tried, would present intractable management problems . . . for the proposal is that there be no trial."); *see also Gunnells v. Grant Thorton, LLP*, 348 F.3d 417, 440 (4th Cir. 2003) (noting the settlement is relevant to a finding of predominance, and recognizing that Rule 23 creates an "interactive" series of considerations to be used in certifying classes).

5. Predominance

As previously discussed herein, Rule 23(a)(2) requires a showing of the existence of "questions of law or fact common to the class." *Fed. R. Civ. P.* 23(a)(2). Rule 23(b)(3) requires the Court to determine whether these common questions of law or fact predominate over any questions affecting only individual class members. This rule tests "whether proposed classes are cohesive

enough to warrant adjudication by representation." *Gariety v. Grant Thornton*, 368 F.3d 356, 362 (4th Cir. 2004). The Supreme Court has instructed that the predominance inquiry "trains on the legal or factual questions that qualify each class member's case as a genuine controversy, questions that preexist any settlement." *Amchem*, 521 U.S. at 623.

Overall, the instant action presents more than a mere common interest in a fair compromise. The entire history of Serzone is common; the drug was formulated, manufactured, and distributed in exactly the same fashion. The common issues – arising from the common course of conduct by the defendant in manufacturing and distributing Serzone, and the common character of the underlying science and the alleged injuries to the Class Members – would be the subject of most of the efforts of the parties and the court in resolving this case. Indeed, the relationship between BMS and the injured claimants is a "distant and impersonal one, involving only the injurious use of an allegedly defective product." Mary J. Davis, *Toward the Proper Role for Mass Tort Class Actions*, 77 OR. L. REV. 157, 164 (1998) (arguing that "consequently, no meaningful difference based on the nature of the parties' relationship exists on which to base liability as might be in other contexts, like medical malpractice or automobile cases"). For all claimants, culpability is the central issue, and that determination focuses upon the actions of BMS.

This case involves one defendant, one product, and one course of conduct confined to a defined time period in which the defendant engaged in behavior that presented virtually identical risk to all the claimants. Questions that are central to the case and common to the class include: (1) Does Serzone cause physical injury and illness? (2) Did BMS conduct appropriate testing of Serzone? (3) Did BMS adequately warn of the adverse effects of Serzone? and (4) Did BMS misrepresent the risk of adverse effects of Serzone? Although Settlement Class Members may have

suffered variant degrees of harm, the proof regarding the dangerous propensities alleged of Serzone is the same for any person seeking to establish liability against BMS. These core liability issues are involved in the claims of all Plaintiffs, and all claims involve common proof.

Still yet, litigation of this matter presents individual issues such as causation and differing state laws. In the context of the settlement, however, such issues are rendered irrelevant, allowing common issues to predominate. Differences in state law, such as those regarding contributory negligence and comparative fault, the learned intermediary doctrine, punitive damages, and the statute of limitations do not destroy class cohesion because the settlement agreement provides for the distribution of benefits based on the objective criteria described in the Schedule of Payments. As this matter involves attorneys representing individual clients from all over the nation, it is noteworthy that not a single attorney raised an objection indicating variances in state law as a basis for disapproving certification of this settlement class.

Moreover, individual issues of causation, such as those regarding physiology, underlying illnesses, and medical history, as well as injuries and damages also abate because the settlement's objective criteria provide for an objective scheme of compensation. Again, not a single objection was raised regarding the settlement agreement's treatment of individual issues of causation. Accordingly, I **FIND** that there are questions of law or fact – involving a common product, defendant, course of conduct, and risk – that are common to the members of the class and that these questions predominate over any questions affecting only individual members.

6. Superiority

In *Amchem*, the Supreme Court stated that Rule 23(b)(3)'s superiority requirement, like predominance, ensures that resolution by class action will "achieve economies of time, effort, and

expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Amchem*, 521 U.S. at 615.

Settling this case as a class action will achieve economies for both the litigants and the court. A class action significantly reduces the overall cost of complex litigation, allowing plaintiffs' attorneys to pool their resources and requiring defendants to litigate all potential claims at once, thereby leveling the playing field between the two sides. *In re Agent Orange Product Liab. Litig.*, 597 F. Supp. 740, 842 (E.D.N.Y. 1984), aff'd, 818 F.2d 145 (2d Cir. 1987). In contrast, if certification of this settlement class were denied, litigating the similar issues in individual lawsuits would consume many more judicial resources than addressing them together in this class action. *In re A.H. Robins*, 880 F.2d at 742. Requiring individual Class Members to file their own suits would cause unnecessary, duplicative litigation and expense, with parties, witnesses and courts required to litigate time and again the same issues, possibly in different forums. *Id.* Moreover, class treatment limits the possibility of inconsistent rulings regarding liability or the appropriate measurement for damages. *Id.* Finally, Class Members will receive prompt and guaranteed compensation for their injuries.

Absent the class procedures, many Class Members may be effectively foreclosed from pursuing their claims. Class actions are often the only means for assuring that defendants who have harmed consumers will not benefit from their unlawful conduct simply because of the magnitude of the misconduct and aggregated harm compared to the small magnitude of individual harm. *Gunnells v. Healthplan Serv., Inc.*, 348 F.3d 417, 426 (4th Cir. 2003). The individual harm is often too minimal to bear the high costs of individual litigation. *Id.* Thus, without the class device, thousands of plaintiffs could be denied their day in court. *Id.* The Supreme Court declared in *Deposit*

Guaranty Nat'l Bank v. Roper, 445 U.S. 326, 339 (1980) that "[w]here it is not economically feasible to obtain relief within the traditional framework of a multiplicity of small individual suits for damages, aggrieved persons may be without any effective redress unless they may employ the class action device."

As for the Fund D claims, which number in the thousands but are of little monetary value, the necessity of class treatment is apparent. Nevertheless, I recognize that the class consists not only of members with claims of little monetary value but also those with monetary values reaching millions of dollars. Members of the class with specific physical injuries whose claims are monetarily significant, particularly the Fund A claimants, have a greater interest than members with no physical injury in retaining control over their own cases, particularly regarding damages issues. Concerns over individual control are significantly alleviated, however, in the context of this particular settlement. The Schedule of Payments incorporates individual issues for the most seriously injured claimants. On an individual basis, Fund A claimants are eligible to receive damages for lost wages and loss of consortium in addition to baseline damage awards reaching millions of dollars. Fund B claimants are also eligible to receive damages for lost wages. Even though both claimants with physical and non-physical injuries are part of the same class, the parties have fashioned a distribution plan that is both fair to the strong plaintiffs and efficient in adjudicating the large number of claimants. Accordingly, I **FIND** class action treatment to be superior in this matter.

VII. Fairness Determination

Rule 23(e)(1)(C) provides that a court may only approve the settlement of a certified class action after determining that it is fair, reasonable, and adequate. While compromise and settlement are favored by the law, "the primary concern addressed by Rule 23(e) is the protection of class

members whose rights may not have been given adequate consideration during the settlement negotiations." *In re Jiffy Lube Securities Litigation*, 927 F.2d 155, 158 (4th Cir. 1991). In *In re MicroStrategy, Inc. Sec. Litigation*, 148 F. Supp. 2d 654 (E.D. Va. 2001), the court noted that approval of a class action settlement is committed to the "sound discretion of the district courts to appraise the reasonableness of particular class-action settlements on a case-by-case basis, in light of the relevant circumstances." *Id.* at 663 (quoting *Evans v. Jeff D.*, 475 U.S. 717, 742 (1986)).

As a preliminary matter in this fairness determination, I am somewhat concerned by the treatment of causation under the terms of the settlement agreement. The settlement agreement here streamlines claims by operation of the Schedule of Payments, which eliminates the need for Class Members to prove causation. In return, BMS achieves greater certainty as to its potential tort liabilities. Several courts have approved similar product liability class action settlements utilizing this approach to causation. For instance, in *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 227 F.R.D. 553, 563 (W.D. Wash. 2004), the court granted final approval to the class action settlement that "effectively nullifie[d]" causation. In *In re Inter-Op Hip Prosthesis Liab. Litig.*, No. 1:01-CV-9000, MDL 1401, 2002 WL 1359693 (N.D. Oh. May 8, 2002), the court granted final approval of a settlement, in which "individual issues relating to causation . . . disappear because the settlement's objective criteria provide for an objective compensation scheme." *See In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. 330, 347 (N.D. Ohio 2001) (granting preliminary approval to settlement). In *In re Diet Drugs Prods. Liab. Litig.*, Nos. 1203, 99-20593, 2000 WL 1222042, at *22 (E.D. Pa. Aug. 28, 2000), the court granted final approval to a settlement in which "[c]lass members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover." In *In re Baxter Healthcare Corp. Gammagard Prods. Liab. Litig.*, Final Order

and Judgment (C.D. Cal. Oct. 5, 2000), the court granted final approval to a settlement that required only proof of infusion with the defendant's product and, if claiming injuries, proof of injury. Finally, in *In re Factor VII or IX Concentrate Blood Prods. Litig.*, Final Order and Judgment relating to Settlement (N.D. Ill. May 8, 1997), the court granted final approval to a settlement that eliminated the need to prove causation, observing that establishing causation would present a significant obstacle to many class members if the case were to go to trial, a fact which supported final approval. *Id.* at ¶ 10(A).

Despite the supporting authority of these other product liability class action settlements which eliminated the need to prove causation, I nevertheless harbor reservations about giving private attorneys the authority to construct such a mechanism for resolving claims. The notion simply hints at opportunity for collusion and nuisance-value awards. In this case, however, my concerns are allayed by: (1) the character and sophistication of the attorneys involved in this matter, notably the Class Counsel and (2) the particularities of the science behind this drug and associated liver injuries. Thus, in this case, allowing attorneys to construct an appropriate claims resolution mechanism may be justified by very careful judicial review.

Unlike some other settlements in which leadership among class counsel has come into being largely outside the control of the court, I carefully selected the attorneys who would later become Class Counsel from a highly qualified pool of attorney applicants shortly after this matter was transferred to this court as an MDL. I selected Carl N. Frankovitch, Marvin W. Masters, Dianne M. Nast and Stanley M. Chesley to represent the class not only because they possess sophisticated legal expertise but also because they exhibit the traits of careful and thoughtful fiduciaries. I also appointed the members of the Plaintiffs' Executive Committee, charged with conducting and

coordinating discovery, and approved BMS' proposed Lead and Liaison Counsel. I am confident in my selection and my approval of these attorneys, and I am able to give significant weight to their assertions that this settlement is the product of hard-fought, arms-length negotiations and that the interests of their clients and the class as a whole have been protected.

Nevertheless, beyond the character and professional record of these attorneys, the class was further protected through a system of checks and balances provided by the other plaintiffs' attorneys representing individual clients across the nation in this matter. There is no incentive fee arrangement in the Settlement Agreement for attorneys representing individual clients. As such, these attorneys are receiving no greater fee benefit under the settlement than they would normally receive. Attorneys representing individual clients, particularly those with contingency fee agreements entered into before the date of the Settlement Agreement, have every incentive to object if the recovery amounts under the settlement are unfair. Significantly, no objections to recovery amounts for Class Members were made. Lastly, I note that while BMS has agreed to pay attorneys' fees, I have and will exercise complete control over the amount that is awarded.

With regard to the unique interplay of science and specific causation in this matter, there are some key scientific conclusions about Serzone and associated liver injuries, which are undisputed in the record, that allow uncertainties regarding causation to be reasonably and adequately dealt with in the compensation calculus of the Schedule of Payments. To begin, the heightened risk of liver injury associated with Serzone was three or four times the estimated background rate of liver failure and that is likely an underestimate due to underreporting. While epidemiological studies show a low incidence of Serzone-related liver failure and injury, these results do strongly suggest more than a mere correlation between the drug and liver damage. Most importantly, with very few exceptions,

liver injuries associated with Serzone will manifest no later than two weeks after the drug has left the body, and patients who have recovered from drug induced liver injury without the need for a liver transplant do not face any residual risk of progressive or future injury if the drug is avoided. (Watkins Aff. ¶ 21, June 3, 2005); *see also* Fairness Hr'g Tr. at 13, June 29, 2005 (argument of Carl Frankovitch). Thus, there is a distinct time frame within which Serzone may have caused a claimant's liver injury.

Given this distinct time frame, a claims resolution mechanism based upon a temporal association between the ingestion of Serzone and the alleged associated injury reflects a reasonable compromise of causation issues. Clearly, Class Counsel, members of the Plaintiffs' Executive Committee, and counsel for BMS had a keen appreciation for causation issues in this case as the record indicates that they carefully scrutinized individual plaintiff fact sheets and medical records as well as all Serzone adverse event reports with the assistance of highly qualified medical experts. The parties indeed took advantage of the distinct time frame they discovered for claims in this case when structuring the Schedule of Payments by incorporating objective requirements of temporal association. With regard to pre-existing liver conditions, which further complicate issues of causation, the parties simply created a lower gradation of payment within a given fund. Coordinately, claimants with no pre-existing liver conditions, who consequently have fewer obstacles in proving causation, fall into the higher gradation of payment within a given fund. I conclude that the parties acted diligently and with great care in designing a schedule of payments that incorporates important considerations of these causation issues.

Because the design of the Schedule of Payments so neatly parallels the unique, underlying science in this matter, my concerns regarding causation are assuaged. While the settlement is not a

perfect substitute for establishing specific causation, the structure of the Schedule of Payments takes us a long way toward it. Accordingly, I **FIND** that the objective criteria in the Schedule of Payments represent a fair and reasonable compromise of causation issues. Such criteria save claimants the burden of establishing causation as a matter of certainty while preventing undesirable recoveries for groundless claims. This compromise supports a finding of hard-fought, arms-length negotiations in this matter that incorporate a critical understanding of the scientific nature of Serzone and associated liver injuries into the Settlement Agreement.

Proceeding from this general fairness consideration to the factors specified by the Fourth Circuit, I note the Court's adoption of a bifurcated analysis, separating the inquiry into a settlement's "fairness" from the inquiry into a settlement's "adequacy." *MicroStrategy*, 148 F. Supp. 2d. at 663 (citing *In re Jiffy Lube Sec. Litig*., 927 F.2d 155, 158-59 (4th Cir. 1991)); *see also Strang v. JHM Mortgage Sec. Ltd. P'ship*, 890 F.Supp. 499, 501 (E.D. Va. 1995). In assessing the fairness of a proposed settlement, the court must consider the following four factors: (a) the posture of the case at the time the settlement was proposed; (b) the extent of discovery that had been conducted; (c) the circumstances surrounding the negotiations; and (d) the experience of counsel in the area of class action litigation. *Id.* at 663-64; *see also Strang,*890 F. Supp. at 501. In determining the "adequacy" of the settlement, the court should look to the following: (a) the relative strength of the plaintiffs' case on the merits; (b) the existence of any difficulties of proof or strong defenses the plaintiffs are likely to encounter if the case goes to trial; (c) the anticipated duration and expense of additional litigation; (d) the solvency of the defendants and the likelihood of recovery on a litigated judgment; and (e) the degree of opposition to the settlement. *Id.* at 665; *see also Strang,*890 F. Supp. at 501.

A. Criteria for Fairness:

1. Posture of the case at the time the settlement was proposed / 2. Extent of discovery

When reviewing a Settlement, courts should consider the stage of the current litigation and the amount of discovery that the parties have completed. *Jiffy Lube*, 927 F.2d, at 159; s*ee also In re Prudential Ins. Co. of Am. Sales Pract. Litig.*, 148 F.3d 283, 319 (3d Cir. 1998). As other courts considering mass tort settlements have observed, this factor is useful in evaluating whether the plaintiffs and their counsel have sufficiently developed the case to appreciate the merits of their claims. *In re Diet Drugs Prods. Liab. Litig*. Nos. 1203, 99-20593, 2000 WL 1222042, at *60 (E.D. Pa., Aug. 28, 2000). There is, however, no minimum or definitive amount of discovery that must be undertaken. *Jiffy Lube*, 927 F.2d at 159.

As outlined earlier in this opinion, this matter was actively litigated for over two years before the settlement was reached. During that time, two committees, the Plaintiffs' Executive Committee and the Discovery Committee, were established to deal with discovery matters in this case. The record indicates that Class Counsel, members of the Plaintiffs' Executive Committee, and the Discovery Committee carefully scrutinized all Serzone adverse event reports, the Serzone New Drug Application (NDA), Amended NDA, Safety Updates, Investigational NDA (IND), Food and Drug Administration Advisory Panel Transcripts, and studies and reports not included in the NDA and/or IND. In total, over one and a half million documents were analyzed. Also, physicians and scientific experts were consulted extensively.

As the breast implant litigation makes clear, realistically estimating the number of claims is critical to insuring the success of any attempt at setting up a claims resolution. *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV94-P-11558-S, MDL 926 (N.D. Ala. Sept. 1, 1994). Thus, extensive discovery in this matter is also evidenced by a sound estimate of the number of

claims, which we have here according to the response data garnered by the returned inventory forms. This also supports the idea that the case was at a point where such reasonable estimates could be made. Accordingly, discovery has been sufficient to give counsel an informed view of the strengths and weakness of the plaintiffs' case.

3. Circumstances surrounding the negotiations; whether settlement is a product of hard-fought, arms-length negotiation

When settlement negotiations began in mid-2003, each side was able to negotiate from a position of knowledge about the merits of the case. Over the course of more than a year, over twenty day-long negotiation sessions were held in New York City and other locations. Scores of telephone meetings were held, and a number of negotiation sessions occurred in conjunction with court proceedings. There is no evidence in the record to suggest, nor do any of the objectors assert, that this settlement agreement was tainted by collusion of the parties. Rather, the settlement agreement in this matter represents the product of hard-fought, arms-length negotiations aided by extensive discovery.

4. Experiences of counsel in the area of class action litigation

As discussed earlier, I am confident in my selection of Class Counsel and my approval of Lead and Liaison Defense Counsel. Carl N. Frankovitch, Marvin W. Masters, Dianne M. Nast and Stanley M. Chesley are nationally recognized members of the complex civil litigation bar and have been involved significantly in major leadership positions in many complex mass tort and personal injury class actions. Similarly, counsel for BMS are members of a nationally recognized law firm, and are also well known in the litigation bar.

B. Criteria for Adequacy:

1. Relative strength of the plaintiffs' case on the merits / 2. Existence of any

difficulties of proof or strong defenses the plaintiffs are likely to encounter if the case goes to trial

"The most important factor to be considered in determining whether there has been such clear abuse of discretion is whether the trial court gave proper consideration to the strength of the plaintiff's case." *Flinn v. FMC Corp*., 528 F.2d 1169, 1172 (4th Cir. 1976). "[I]f the settlement offer was grossly inadequate, it can be inadequate only in light of the strength of the case presented by plaintiffs." *Id.* at 1172 (quoting *City of Detroit v. Grinnell Corp*., 495 F.2d 448, 455 (2d Cir. 1974). As the court in *MicroStrategy* noted, "while Class Counsel express confidence in the strength of plaintiffs' case on the merits, 'the complexities and uncertainties characteristic of class action securities litigation, and the associated expenses of such litigation, make it appropriate for . . . plaintiffs to compromise their claims pursuant to a reasonable settlement.'" *In re Microstrategy, Inc. Securities Litigation*, 148 F. Supp. 2d 654, 665(E. D. Va. 2001) (quoting *South Carolina Natl. Bank v. Stone*, 139 F.R.D. 335, 340 (D. S.C. 1991). A trial necessarily involves the risk that Plaintiffs and the Class would obtain little or no recovery. *Weiss v. Mercedes-Benz*, 899 F. Supp. 297, 1301 (D. N.J. 1995) ("The risks surrounding a trial on the merits are always considerable.")

Class Counsel assert that plaintiffs' claims are meritorious, but also admit that there are obvious hurdles in establishing proof of liability and damages. At trial, plaintiffs would have to demonstrate, through the presentation of expert testimony, that Serzone causes the type of injuries alleged and that it, in fact, caused the injuries suffered by Plaintiffs. This is complicated by issues of individual physiology and pre-existing medical conditions as well as the complexities of depression and liver diseases.

Even if it is shown that the drug did cause the claimed injury, BMS has substantial defenses that create uncertainties about liabilities and damages. Indeed, BMS raised fifty-seven defenses in

its answer to the class action complaint. Most notably, BMS could raise defenses such as the learned intermediary doctrine, statute of limitations, statute of repose, and failure to mitigate damages to bar or reduce any damages sought by claimants. Plaintiffs indeed present meritorious claims, and the settlement eliminates several, significant obstacles to their recoveries. The record contains evidence supporting the valuation of those recoveries in the Schedule of Payments, and no objections indicate otherwise. Accordingly, I find these considerations weigh in favor of the adequacy of the settlement.

3. Anticipated duration and expense of additional litigation

This case involves thousands of Class Members. It is permeated by complicated medical and scientific issues. Trials would necessarily be expensive and time consuming. See *In re Prudential Ins. Co. of America Sales Practices Litigation*, 148 F.3d 283, 318 (3rd Cir.1998).

4. Solvency of the defendants and likelihood of recovery on a litigated judgment

The solvency of the defendant may be relevant to determining the adequacy of a settlement if it appears that the defendant would not be able to satisfy a litigated judgment, thus making settlement the only means for claimants to recover at all. In this case, however, probabilities weigh in favor of BMS being able to satisfy most judgments that plaintiffs might have obtained against it. In 2004, BMS reported its net sales to be $19.38 billion. In both 2003 and 2004, Fortune magazine listed BMS as number 92 in its Fortune 500, with more than $20 billion in revenues reported. Since the remaining factors weigh in favor of finding the Settlement to be adequate, this factor may be given little weight. *See Henley v. FMC Corp*., 207 F. Supp. 2d 489, 494 (S.D. W. Va. 2002).

5. Reaction of Class Members to the proposed settlement; degree of opposition to the settlement

"The attitude of the members of the class, as expressed directly or by failure to object, after notice, to the settlement, is a proper consideration for the trial court." *Flinn v. FMC Corp.*, 528 F.2d 1169, 1173 (4th Cir. 1976). "While approval of a proposed class settlement is not a matter to a plebiscite, the views of putative class members are certainly relevant and entitled to great weight." *In re Silicone Gel Breast Implant Liability Litig.*, No. CV94-P-11558-S, MDL 926 (N.D. Ala. Sept. 1, 1994). If class members opt-out, the court should examine the circumstances to determine whether the opt-outs reflect an organized campaign or the sentiments of the class at large. MANUAL FOR COMPLEX LITIGATION (Fourth) § 21.631 (2004). Nevertheless, "[a] settlement is not unfair simply because a large number of class members oppose it." *Flinn*, 528 F.2d, at 1173 (4th Cir. 1976).

In the instant case, 6,524 inventory claims forms have been timely filed and 120 were received after the deadline. Opposite this favorable response, 2,536 opt-outs have been timely filed, with 22 arriving after the deadline. BMS asserts that the members who have excluded themselves are predominantly represented by one consortium of counsel and that they fall into the category of Fund D claims. Seventeen objections were filed, but most were tailored to individual interests or particular procedural aspects of the Settlement Agreement. For reasons noted earlier in the discussion of objections, none of these objections raised any significant bar to my approval of the proposed settlement. Despite the objector's arguments, I **FIND** that this settlement is fair and adequate.

VIII. Conclusion

For the foregoing reasons, the court: (1) **SUSTAINS** the objection regarding the proper civil standard of review in the magistrate's review of the claims process and **ORDERS** substitution of the

standard "beyond a reasonable doubt" with "clear error" in Paragraph 7.9 of the Third Amended Settlement Agreement; (2) **OVERRULES** the remaining objections to the settlement agreement and proposed class; (3) **APPROVES** the withdrawal of William Edwin Collard, Jr.'s objection and the withdrawal of Certain Third Party Payers' and the Blue Cross Plans' Motions to Intervene for Purposes of Presenting Objections and set forth objections to the Proposed Settlement Agreement; (4) **CERTIFIES** the proposed class upon finding that the class satisfies Rule 23(a) and Rule 23(b)(3); and (5) **APPROVES** the proposed settlement upon finding that the settlement is fair, reasonable and adequate for purposes of Rule 23(e).

The court **DIRECTS** the Clerk to send a copy of this Order to Defendant's Liaison Counsel and Plaintiffs' Liaison Counsel, and **DIRECTS** the Clerk to post this published memorandum and opinion at http://www.wvsd.uscourts.gov.

ENTER: Sept. 2, 2005

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE